JAN - 7 2005

510(k) Summary
Emit® II Plus Ecstasy Assay and Emit® II Plus Ecstasy Calibrators / Controls

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K043028

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation

Manufacturer:	Dade Behring Inc. 20400 Mariani Ave. Cupertino, CA 95014
Contact Information:	Dade Behring Inc. P.O. Box 6101 Newark, DE 19714 Attn: Yuk-Ting Lewis Tel: 302-631-7626
Date of Preparation:	Nov. 1, 2004

2. Device Name / Classification

Emit® II Plus Ecstasy Assay: Amphetamine Test System
Classification: Class II (862.3100)

Emit® II Plus Ecstasy Calibrators / Controls: Clinical Toxicology Calibrator
Classification: Class II (862.3200)

Emit® II Plus Ecstasy Calibrators / Controls: Clinical Toxicology Control
Classification: Class I (862.3280)

3. Identification of the Legally Marketed Device

DRI® Ecstasy Enzyme Immunoassay, K012110
DRI® Ecstasy Urine Calibrators, K012109
Emit® Calibrator/Control, K993755.

4. Device Description

Assay
The Emit® II Plus Ecstasy Assay is a homogeneous enzyme immunoassay used for the analysis of specific compounds in human urine. The assay is based on competition between drug in the specimen and drug labeled with recombinant glucose-6-phosphate dehydrogenase (rG6PDH) for antibody binding sites. Enzyme activity decreases upon binding to the antibody, so the drug concentration in the specimen can be measured in terms of enzyme activity. Active enzyme converts nicotinamide adenine dinucleotide (NAD) to NADH in the presence of glucose-6-phosphate (G6P), resulting in an absorbance change that is measured spectrophotometrically. Endogenous serum G6PDH does not interfere because the coenzyme NAD functions only with the bacterial (*Leuconostoc mesenteroides*) enzyme employed in the assay.

Calibrator / Control
The Emit® II Plus Ecstasy Calibrators / Controls are liquid, four-level calibrators prepared from MDMA, urine and preservatives.

5. Device Intended Use

Assay
The Emit® II Plus Ecstasy Assay is a homogeneous enzyme immunoassay with a 300 ng/mL or 500 ng/mL cutoff. The assay is intended for use in laboratories for the qualitative and/or semiquantitative analysis of methylenedioxymethamphetamine (MDMA) and closely related drugs in human urine. Emit® II Plus assays are designed for use with a number of chemistry analyzers.

The Emit® II Plus Ecstasy Assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug-of-abuse test result, particularly when preliminary positive results are used.

Calibrator / Control
The Emit® II Plus Ecstasy Calibrators / Controls are used in the calibration of the Emit® II Plus Ecstasy Assay. These standards may also be used as quality control materials based upon the Ecstasy assay cutoff.

6. Medical device to which equivalence is claimed and comparison information

Assay

The Emit® II Plus Ecstasy Assay is substantially equivalent in intended use and methodology to the Microgenics DRI® Ecstasy Enzyme Immunoassay (K012110). Both devices are enzyme immunoassays intended for use in the qualitative and semiquantitative determination of ecstasy drugs in human urine. The Emit® II Plus Ecstasy Assay has two cutoffs: 300 ng/mL and 500 ng/mL, while the DRI® Assay has a single cutoff at 500 ng/mL.

Comparison Information

A. 300 ng/mL cutoff

One hundred (100) urine specimens were tested with the Emit® II Plus Ecstasy Assay on the SYVA®-30R Biochemical System. Results were compared to the reference method (GC/MS). The Assay used a cutoff level of 300 ng/mL for MDMA.

Fifty-seven (57) samples were found to be positive by GC/MS (≥200 ng/mL MDMA, MDEA or MDA using UK guidelines) and fifty-five (55) were found to be positive by the Emit® II Plus Ecstasy Assay.

Forty-three (43) samples were found to be negative by GC/MS (<200 ng/mL MDMA, MDEA or MDA using UK Guidelines) and forty-five (45) were found to be negative by the Emit® II Plus Ecstasy Assay.

There were two (2) discrepant samples. Both discrepant samples were identified as negative by the Emit® II Plus Ecstasy Assay and positive by GC/MS. The discrepant samples were within ±50% of the cutoff.

Qualitative Results at the 300 ng/mL Cutoff

		Reference Method GC/MS	
		Positive	Negative
Emit® II Plus Ecstasy Assay	Positive	55	0
	Negative	2	43

Percent Agreement: 98% (98 / 100)

B. 500 ng/mL cutoff

One hundred (100) urine specimens were tested with the Emit® II Plus Ecstasy Assay on the SYVA®-30R Biochemical System. Results were compared to the reference method (GC/MS). The Assay used a cutoff level of 500 ng/mL for MDMA.

Fifty-seven (57) samples were found to be positive by GC/MS (≥250 ng/mL MDMA, MDEA or MDA using proposed SAMHSA Mandatory Guidelines) and fifty-three (53) were found to be positive by the Emit® II Plus Ecstasy Assay.

Forty-three (43) samples were found to be negative by GC/MS (<250 ng/mL MDMA, MDEA or MDA using proposed SAMHSA Mandatory Guidelines) and forty-seven (47) were found to be negative by the Emit® II Plus Ecstasy Assay.

There were four (4) discrepant samples. All discrepant samples were identified as negative by the Emit® II Plus Ecstasy Assay and positive by GC/MS. The discrepant samples were within ±50% of the cutoff.

Qualitative Results at the 500 ng/mL Cutoff

		Reference Method GC/MS	
		Positive	Negative
Emit® II Plus Ecstasy Assay	Positive	53	0
	Negative	4	43

Percent Agreement: 96% (96 / 100)

Calibrators / Controls

The Emit® II Plus Ecstasy Calibrators / Controls are substantially equivalent in intended use and methodology to the Microgenics DRI® Ecstasy Urine Calibrators (K012109). Both devices are multi-levels controls used for calibrating their respective assays.

The Emit® II Plus Ecstasy Calibrators / Controls are liquid and contain MDMA in the following concentrations: Level 1 – 150 ng/mL, Level 2 – 300 ng/mL, Level 3 – 500 ng/mL, and Level 4 – 1000 ng/mL. The MDMA concentration is traceable to a Master Lot and to confirmation by GC/MS.

Shelf life was evaluated by testing each calibrator / control level in their final containers. Testing was performed on the SYVA®-30R analyzer.

Excerpted from Emit® II Plus Ecstasy Assay 510k, K043028

Table 1: Comparison of features of the Assays

Feature	**DRI® Ecstasy Enzyme Immunoassay, K012110**	**Emit® II Plus Ecstasy Assay**
Intended Use	The DRI® Ecstasy Enzyme Immunoassay is a homogeneous enzyme immunoassay intended for the qualitative or semiquantitative determination of ecstasy drugs in human urine. The assay provides a simple and rapid analytical screening procedure for detecting ecstasy drugs at a cutoff level of 500 ng/mL. This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography / mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.	The Emit® II Plus Ecstasy Assay is a homogeneous enzyme immunoassay with a 300 ng/mL or 500 ng/mL cutoff. The assay is intended for use in laboratories for the qualitative and/or semi-quantitative analysis of methylenedioxymethamphetamine (MDMA) and closely related drugs in human urine. Emit® II Plus Assays are designed for use with a number of chemistry analyzers. The Emit® II Plus Ecstasy Assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used to obtain a confirmed analytical result. Gas chromatography / mass spectrometry (GC/MS) is the preferred confirmatory method. Other clinical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug-of-abuse test result, particularly when preliminary positive results are used.
Principle	Homogeneous enzyme immunoassay	Homogeneous enzyme immunoassay
Antibody	Monoclonal anti-MDMA antibody.	Sheep polyclonal antibodies to methylenedioxymethamphetamine (MDMA).
Reagent Composition	***Antibody/Substrate Reagent:*** Monoclonal anti-MDMA antibody, G6P, NAD in tris buffer with sodium azide as a preservative. ***Enzyme Conjugate Reagent:*** Methylenedioxymethamphetamine (MDMA) labeled with G6PDH, tris buffer, and sodium azide as a preservative.	***Antibody/Substrate Reagent A:*** Sheep polyclonal antibodies to methylenedioxymethamphetamine (MDMA), bovine serum albumin, G6P, NAD, preservatives and stabilizers. ***Enzyme Reagent B:*** Methylenedioxyamphetamine (MDA) labeled with bacterial G6PDH, tris buffer, bovine serum

		albumin, preservatives and stabilizers.
Cutoff	500 ng/mL	300 ng/mL and 500 ng/mL
Semiquantitative Range	22* – 1000 ng/mL (* estimation based on the reported sensitivity)	100*– 1000 ng/mL (* based on recovery study)
Sensitivity	22 ng/mL	75 ng/mL
Specimen Type	Human urine	Human urine
Instrument	Chemistry analyzers	Chemistry analyzers

Table 2: Comparison of features of the Calibrators

Feature	**DRI® Ecstasy Urine Calibrators, K012109**	**Emit® II Plus Ecstasy Calibrators / Controls**
Intended Use	The DRI® Ecstasy urine calibrators are intended for the calibration of the DRI® Ecstasy Immunoassay.	The Emit® II Plus Ecstasy Calibrators / Controls are used in the calibration of the Emit® II Plus Ecstasy Assay. These standards may also be used as quality control materials based upon the Ecstasy assay cutoff.
Matrix	Methylenedioxymethamphetamine, human urine.	Methylenedioxymethamphetamine (MDMA), human urine, preservatives.
Calibrator Levels	250 ng/mL Calibrator 500 ng/mL Calibrator 750 ng/mL Calibrator 1000 ng/mL Calibrator	Level 1: 150 ng/mL MDMA Level 2: 300 ng/mL MDMA Level 3: 500 ng/mL MDMA Level 4: 1000 ng/mL MDMA
Form	Liquid	Liquid
Instrument	Chemistry analyzers	Chemistry analyzers

Table 3: Comparison of features of the Controls

Feature	**Emit® Calibrator/Control K993755**	**Emit® II Plus Ecstasy Calibrators / Controls**
Intended Use	The Emit® Calibrators/Controls are used in the calibration of the Emit® II Plus drugs-of-abuse assays. These standards may also be used as quality control materials based upon specified assay cutoff levels. The Emit® Calibrators/Controls are used for the Emit II Plus Barbiturate, Benzodiazepine, Cannabinoid, Cocaine Metabolite, Methadone, Methaqualone, Monoclonal Amphetamine/Methamphetamine, Opiates, Phencyclidine and Propoxyphene Assays.	The Emit® II Plus Ecstasy Calibrators / Controls are used in the calibration of the Emit® II Plus Ecstasy Assay. These standards may also be used as quality control materials based upon the Ecstasy assay cutoff.
Matrix	Benzoylecgonine, lormetazepam, methadone, d-methamphetamine, Methaqualone, morphine, 11-Δ9-THC-9-COOH, phencyclidine, propoxyphene, secobarbital, human urine, preservatives.	Methylenedioxymethamphetamine (MDMA), human urine, preservatives.
Calibrator Levels	Level 0 – drug free Level 1 Level 2 Level 3 Level 4 Level 5 Contains multiple drugs in varying concentrations	Level 1: 150 ng/mL MDMA Level 2: 300 ng/mL MDMA Level 3: 500 ng/mL MDMA Level 4: 1000 ng/mL MDMA
Form	Liquid	Liquid
Instrument	Chemistry analyzers	Chemistry analyzers

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN - 7 2005

Yuk-Ting Lewis
Regulatory Affairs and Compliance Manager
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714

Re: k043028
Trade/Device Name: Emit® II Plus Ecstasy Assay
Emit® II Plus Ecstasy Calibrator / Control Level 1
Emit® II Plus Ecstasy Calibrator / Control Level 2
Emit® II Plus Ecstasy Calibrator / Control Level 3
Emit® II Plus Ecstasy Calibrator / Control Level 4
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ, DLJ, DIF
Dated: November 2, 2004
Received: November 3, 2004

Dear Yuk-Ting Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Cornelia B. Rooks

Cornelia B. Rooks, MA
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043028

Device Name: **Emit® II Plus Ecstasy Assay**
Emit® II Plus Ecstasy Calibrator / Control Level 1
Emit® II Plus Ecstasy Calibrator / Control Level 2
Emit® II Plus Ecstasy Calibrator / Control Level 3
Emit® II Plus Ecstasy Calibrator / Control Level 4

Indications For Use:

The Emit® II Plus Ecstasy Assay is a homogeneous enzyme immunoassay with a 300 ng/mL or 500 ng/mL cutoff. The assay is intended for use in laboratories for the qualitative and/or semiquantitative analysis of methylenedioxymethamphetamine (MDMA) and closely related drugs in human urine. Emit® II Plus Assays are designed for use with a number of chemistry analyzers.

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Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K043028